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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,072	01/15/2002	Ralph M. Steinman	MER-011CN/112917-144	7452
43852	7590	05/19/2006	EXAMINER	
MERIX BIOSCIENCE, INC. 4233 TECHNOLOGY DRIVE DURHAM, NC 27704			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: 1644

DETAILED ACTION

1. In view of Applicant's amendment, filed 2/28/06, all previous rejections and objections have been withdrawn.
2. Claims 1 and 5 have been amended.
Claims 1-6 and 10-12 are being acted upon.
3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

A) The list of cytokines employed in the methods of Claims 6 and 10 has no antecedent basis in the specification.

The specification must be amended to include said limitations.

4. The following are new grounds of rejection.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

Regarding Claim 6, the method of the claims as originally presented recited a single step method. Claim 1, from which Claim 6 depends, now recites a multi-step method. The use of the cytokines of Claim 6 in the second step, i.e., as the "composition" (which is employed only in the second step), is not disclosed in the specification.

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Regarding Claim 10, a specific range of concentrations of GM-CSF is disclosed in the specification at page 16 as being used in the first step, i.e., the production of immature DCs, and not in the second step, i.e., as the "composition" of Claim 6 (from which Claim 10 depends).

7. Claims 1-6 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the generic, i.e., from any source, cytokines, e.g., GM-CSF, IL-4, IL-13, TNF- α , of Claims 1, 5, 6, and 10.

The specification discloses in a generic sense, i.e., the sense of the claims, only the use of specific cytokines, e.g., GM-CSF, IL-4, IL-13, of unknown sources. In the examples numerous human cytokines, e.g., GM-CSF, IL-4,, IL-6, IL-13, stem cell factor, etc., including some recombinant cytokines, e.g., rh-IL-4, are disclosed. The method of the claims, however, would encompass the use of cytokines from any sources, e.g., baboons to wombats, cytokines clearly not adequately described in the instant specification. One of skill in the art would conclude therefore that the specification fails to disclose a representative number of species to describe the genus of specific cytokines employed in the method of the instant claims. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

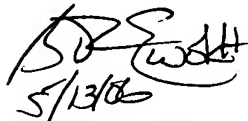
8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from

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7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.



5/13/06

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